JUN 14 2000

510(k) Summary of Safety and Effectiveness

Date:

April 5, 2000

Submitter:

GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

David Wahlig
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems, Inc.
Phone: (414) 362-2090
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Device: Trade Name:

Clinical Information Center (CIC)

Common/Usual Name:

Central Station Monitoring System

Classification Names:

21 CFR 870.2450 Display, Cathode-ray Tube, Medical

Predicate Devices:

K901072 Centralscope 12
K991786 MARS Unity Workstation
K992637 MUSE CV

Device Description:

The CIC is based on a standard PC platform and provides centralized monitoring of all patients connected to GE Marquette monitors and telemetry transmitters. It may be configured to display up to four real-time waveforms per patient for up to 16 patients.

Controls include the use of a computer mouse, keyboard and optional touch screen for precise touch control. Optional writers for the purpose of graphing waveforms and printing patient information include a 2" Direct Digital Writer or a laser printer.

Intended Use:

The Clinical Information Center (CIC) Central Station is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use is to provide clinicians with adult, pediatric and neonatal patient data in a centralized location within a hospital or clinical environment.

The CIC is intended to collect information from a network and display this data. This data includes physiological, patient demographic and / or other non-medical information.

Physiological parameters and waveforms from GE Marquette monitors and telemetry systems can be displayed and printed from the CIC. Beat to beat patient information for all parameters and waveforms from the bedside and telemetry systems can be displayed.

The CIC supports the ability to access information from GE Marquette products in a web browser format. Additionally, CIC supports the ability to access patient information collected from the Unity™ network and stored on a network server.

Technology:

The Clinical Information Center computer platform is a commercially available PC running the Microsoft Windows NT Workstation. The CIC employs the same functional technology as the predicate devices.

Test Summary:

The CIC platform and its applications comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the CIC is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2000

Mr. David Wahlig
Corporate Regulatory Affairs
GE Marquette Medical Systems
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K001112
Trade Name: GE Marquette Clinical Information Center, GE Marquette CIC
Regulatory Class: II (two)
Product Code: 74 DXJ
Dated: April 5, 2000
Received: April 6, 2000

Dear Mr. Wahlig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Center for Device Evaluation
Center for Devices and Radiological
Health

Enclosure

510(k) Number (if known): 510(k) filed on April 5, 2000

Device Name: Clinical Information Center (CIC) Central Station

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001112

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)